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The Impact of Scheduled Meal Breaks on ICU Nurses

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BY

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This practice innovation project is approved as a credible and independent investigation by a candidate for the Doctor of Nursing Practice degree and is acceptable for meeting the project requirements for this degree. Acceptance of this practice innovation project does not imply that the conclusions reached by the candidate are necessarily the conclusions of the major department.

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Abstract

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Ericka Privitt

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The goal of this practice improvement project was to evaluate the impact of scheduling meal breaks for intensive care unit nurses at a Midwestern hospital. A literature review identified stress a main source for burnout and the nursing shortage. Recommendations for the creation of a healthy work environment were found and a program to schedule meal breaks was implemented over a nine week period. The Meal Break Impact Survey was utilized to gather pre and post-survey data. The following data was collected on the Meal Break Impact Survey: (a) demographics; (b) questions in Likert scale response on availability, access, beliefs, length, and conditions around meal breaks; and (c) one free text box on participants experience with meal break initiative on post-survey. Data was also collected from the hospital's scheduling analyst on percentage of shifts that were clocked as no meal breaks received. Pre-survey completion was 41% and completed post-surveys were 39% of the intended population. Statistical significance was found with a $p < 0.05$ between pre and post-survey on question number 19, *I am satisfied with my ability to take a meal break during work*. The percentage of clocked missed meal breaks decreased from an average of clocked no meal breaks 8.25% to 4.65% during the intervention months. Significance was found in the effort to improve access to meal breaks and recommendations are to continue to encourage planning meal breaks for intensive care unit nurses.

Keywords: nurse stress, occupational stress, communication conflict, role stress in nursing, medication errors, eustress, distress in nurses, job satisfaction, healthy work environment for nurses, stress in critical care nurses, compassion fatigue and nursing shortage.

List of Abbreviations

ACLS…….Advanced Cardiovascular Life Support

CINAHL……Cumulative Index to Nursing and Allied Health

CPR……...Cardiopulmonary resuscitation

DNP…….…..Doctor of Nursing Practice

DON……..Director of Nursing

HUC……..Health Unit Clerk

ICU…….....Intensive Care Unit

IOM……...Institute of Medicine

IRB…….....Internal Review Board

LCT……...Lewin's Change Theory

MBIS…….....Meal Break Impact Survey

NDNQI……..National Database of Nursing Quality Indicators

PALS……..…Pediatric Advanced Life Support

PICOT……..Population, Intervention, Comparison, Outcome, Time

PIP…….....Practice Innovation Project

RN…….Registered RN

SCDNT……..Self-Care Deficit Theory

SDSU…….South Dakota State University

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Chapter I

The Impact of Scheduled Meal Breaks on ICU Nurses

Introduction

Nurses frequently report working shifts that do not allow time for bathroom or meal breaks and result in leaving shifts physically and emotionally exhausted (Purcell, Kutash, & Cobb, 2011). Nurses are refusing to work under these current work environments and are leaving the nursing profession (Buchan & Aiken, 2008). Stress was listed as the most reported catalyst and the creation of a healthy work environment is the most recommended solution to this problem (Admi & Moshe-Eilon, 2010; Riahl, 2011).

Stress in the work place is an unfortunate norm in today's society. It has negative consequences that are detrimental to the health of the employee and decreases productivity for the organization. Occupational stress is a multifactorial and multidimensional concern for work environments for today's work force (Riahl, 2011). Stress is largely based on a subjective perception by the individual. Perception presents a unique challenge that makes stress difficult to define and reduce in the work environment (Admi & Moshe-Eilon, 2010).

Riahl (2011) states "the nursing profession is one of the most stressful occupations" (p.727). Nurses, compared to other professions, are exposed to more than the usual amount of expected stress (Hsu, Chen, Yu, & Lou, 2010). Nurses, especially Intensive Care Unit (ICU) nurses, are currently practicing under monumental stressors in today's healthcare settings (Mealer, Jones, & Moss, 2012; Purcell et al., 2011). These various stressors include issues such as increased work demands, short staffing, lack of

proper supplies, lack of proper support from employers, poor relationships between co-workers, role conflict, patient conflict, family conflict, death, dying, and suffering (Admi &Moshe-Eilon, 2010). Ritter (2011) reports stressors in the nurses work environment delay or prevent them from accomplishing basic self-care tasks such as meal and bathroom breaks.

Stressors will continue to deplete the nursing profession of experienced nurses and threaten quality of care to patients if not effectively managed. The creation of a healthy work environment for nurses is a practical approach to manage stressors. Specifically, ensuring nurses are able complete basic necessities of life with scheduled meal breaks (Ritter, 2011). A scheduled meal break provides a foundation that is instrumental to the reduction of occupational stress in nurses and the promotion of a healthy work environment (Paris & Terhaar, 2011).

Significance of problem

Occupational stress has been declared a worldwide epidemic according to the World Health Organization and is a leading contributing source of the current nursing shortage (Riahl, 2011). Occupational stress is causing nurses, who represent the majority of the healthcare professionals with over three million members, to leave the workforce at alarming rates and critically depleting the nursing workforce (Buchan & Aiken, 2008; Institute of Medicine [IOM], 2010). The nursing shortage continues to increase and is a direct threat to patient care. The American Hospital Association projects a shortage of nearly one million nurses by the year 2020 (Purcell et al., 2011).

As the nursing shortage grows the patient population increases and grows more complex than ever before (IOM, 2010). The IOM (2010) reports the effects of healthcare

changes are producing more numerous complex patients without providing for lower nurse to patient ratios. The baby boomer generation functions as a double threat to the profession of nursing. The baby boomer nurses not only take their expertise, but also increase the patient population as they retire. The result of this double effect is the existing nursing population being asked to work longer and harder without relief, resources, or support (Buchan & Aiken, 2008; Mason, Leslie, Lyons, Walke, & Griffin, 2014).

Buchan and Aiken (2008) emphasize that the shortage does not constitute a failure of qualified nurses; rather it reflects nurses who refuse to work under current stressful work environments. Ritter (2011) found the simplest needs such as food, water, and bathroom breaks are often postponed or neglected by nurses resulting in physical and emotional damage to nurses. Neglect of the nurse's basic physiological needs for life can have grave consequences to the nursing force and patient population (Ritter, 2011).

ICU Nurses are found to have an increased level of stress when compared to ward, staff or clinic nurses (Mealer et al., 2012; Purcell et al., 2011). The nature of caring for patients that are critically ill or traumatically injured places ICU nurses at an increased rate of exposure to occupational stress. ICU nurses are responsible for helping patients and their families manage crisis situations that can threaten or alter lives. These repeated exposures to traumatic circumstances place ICU nurses at increased risk of burnout and compassion fatigue (Mason et al., 2014). Traumatic exposures to occupational stressors are detrimental to both nurses and patients (Wlodarczyk & Lazarewicz, 2011). Reduction of stress in the ICU nursing communities needs to be

effectively managed to protect nurses, patients, and healthcare organizations (Mealer et al., 2012).

Nursing burnout, nursing shortage, patient safety, and recent changes to health care reform are forcing nursing leaders to address occupational stress in nurses (Buchan & Aiken, 2008; Riahl, 2011; Vollers, Hill, Roberts, Ambaugh, & Brenner, 2009). Nurses under stress cost the economy billions of dollars in lost revenue and productivity while placing patients at risk for medical errors (Karga, Kiekkas, Aretha, & Lemonidou, 2011). The International Council of Nurses acknowledges the impact of stress in the work environment for nursing and has taken a stand to encourage the creation of healthy work environment's for nurses (Vollers et al., 2009).

Paris and Terhaar (2011) successfully implemented a meal and non-meal break initiative to promote a healthy work environment. Their performance improvement study embodied Maslow's theory of hierarchy of human needs. They adapted Maslow's theory in the development of a visual tool (Figure 1) that identified nursing practice needs in accordance with the hierarchy of human needs. This tool was created as a map to ensure physiological needs are met within the nursing staff before attempting to address other higher needs (Paris & Terhaar, 2011).

Meal breaks are identified as an area for improvement within the practice innovation project (PIP) population. Meal breaks were not scheduled in the ICU where the PIP was implemented. Stakeholders expressed concern of the high amount of meal breaks that are being missed as evidenced by missed breaks on time cards (Table 1). According to the facilities scheduling analyst, clocked no meal breaks averaged 8.58% of nursing shifts for January through August 2014 (D. Cavanaugh, personal communication,

September 2, 2014). Facilitators and stakeholders admitted stress and workload contributed to the lack of meal breaks taken. The PIP stakeholders stated a need for a program that will provide structure and encouragement to improve access to meal breaks (A. Mills, personal communication, April 28, 2014; R. Haxton, personal communication, May 27, 2014).

Figure 1

Hierarchy of Nursing Practice Environment Needs. Retrieved from: **http://img.medscape.com/article/736/441/736441-fig1.jpg**

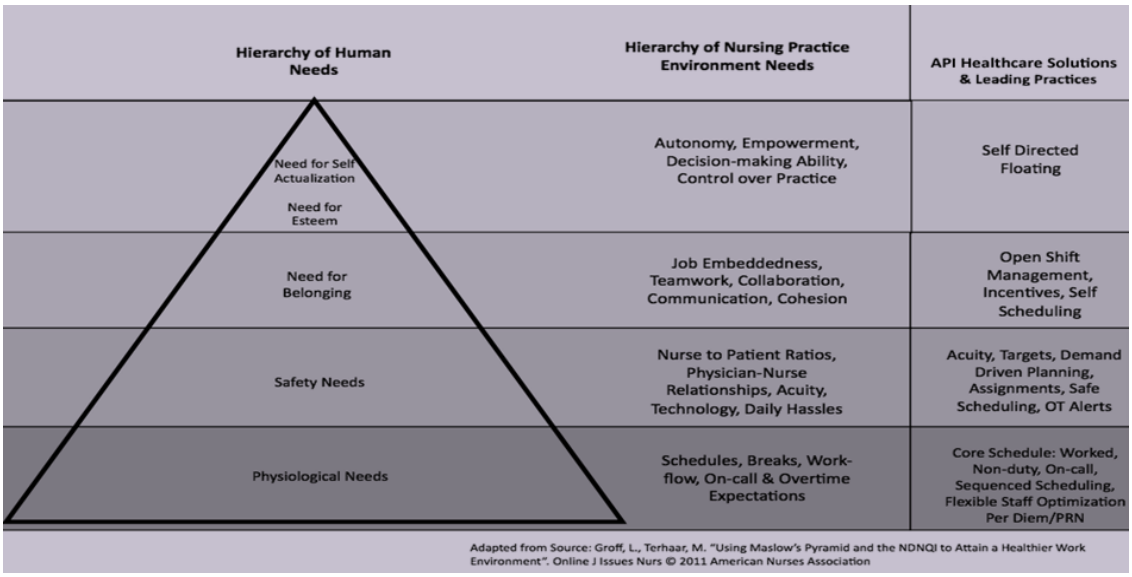
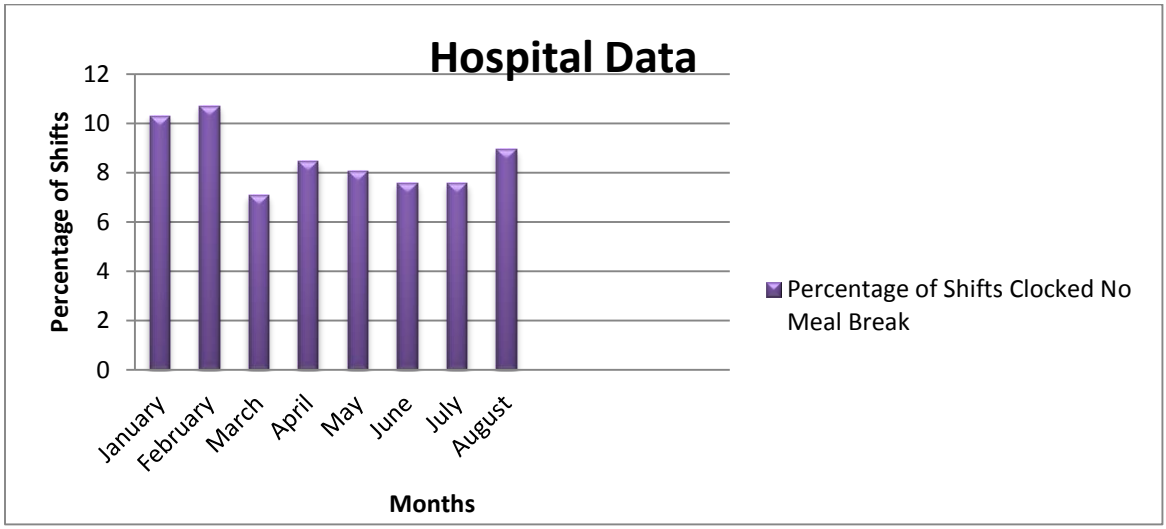


Table 1a

Clocked no meal break for ICU nurses at PIP location



Clinical question

The PICOT (population, intervention, comparison, outcome, time) clinical question will offer an evidenced based focus to implement a system for ICU nurses to schedule meal breaks in an attempt to support a healthy work environment and potentially lighten stressors (Melnyk & Fineout-Overholt, 2010). Meal breaks are often postponed, inadequate or missed due to the extensive workload and stress of the ICU nurse (A. Mills, personal communication, April 28, 20014; R. Haxton, personal communication, May 27, 2014). Meal breaks provide an opportunity for nurses to break away from patient care and offer self-care which can help alleviate stressors from ICU nurses (Paris & Terhaar, 2011). This proposal will answer the following question: *In ICU nurses, what is the impact of scheduled meal breaks compared to nurses who didn't have scheduled meal breaks over four weeks.*

Research Question

The research question for this PIP is: *What is the impact of scheduled meal breaks on ICU nurses as measured by the Meal Break Impact Survey compared to unscheduled meal breaks over four weeks?*

Purpose of the study

The purpose of the study seeks to explore the impact of meal breaks on ICU nurses when nurses are able to schedule meal breaks at the beginning of their shifts during shift change report. The objective is to improve nurse's access to receive 30 minutes for meal break with their worked shift. This project will contribute to the discipline of nursing by identifying essential ways to establish self-care and promote healthy work environments for nurses (Admi & Moshe-Eilon, 2010; Brinkert 2010; Riahl, 2010; Vollers et al., 2009).

Definitions

Stress Classification. Admi and Moshe-Eilon (2010) define stress as a "complex, multi-dimensional phenomenon focusing on a particular dynamic relationship between a person and his/her environment" (p. 152). Riahl (2011) refers to stress as "any force that pushes a psychological or physical factor beyond its range of ability, producing strain within an individual" (p.722). Stress is largely based on a subjective perception by the individual (Admi & Moshe-Eilon).

Nurse. The nursing profession encompasses multi-educational levels. Diploma, associate, bachelors, masters, and doctorate level nursing degrees all fall under the title of nurse (Altmann, 2011). The title of nurse will be correlated with registered nurse for this project.

ICU. The term ICU refers to the Intensive Care Unit. The ICU in this study will include four separate units within the ICU department. The units will include a medical ICU, coronary ICU, surgical ICU and transitional ICU.

Meal breaks. Meal breaks for the institution in the study are currently unscheduled. Unscheduled meal breaks can be defined as meal breaks that are taken by the nurse when they are able to be free from tasks and have a nurse available to cover patients for them. Scheduled meal breaks will be defined as meal breaks at a specific time that the nurse declares at the beginning of their shift during shift change report. Inadequate meal breaks consist of meal breaks that do not provide a 30 minute break during the work shift in which the nurse can sit down, relax, and be free from patient care.

Chapter 2: Review of Literature and Model of Evidence-Based Care

A comprehensive literature review was conducted using EBSCOHost and Cumulative Index to Nursing and Allied Health (CINAHL) via Hilton M. Briggs Library of South Dakota State University. The literature was reviewed according to the John Hopkins Appraisal Tool (2012) and focused on the cause and effective treatment of stress in nursing. Key words searched were; *nurse stress*, *occupational stress*, *communication conflict, role stress in nursing, medication errors, eustress, distress in nurses, job satisfaction, healthy work environment for nurses, stress in critical care nurses, compassion fatigue* and *nursing shortage*. Articles range from 2005 to 2014, providing a nine year span with a wealth of research findings on stress in nursing. An inclusion criterion was used to narrow the range of information and included English language, journal articles from 2005-2014 and all key words listed above related to nursing. Exclusion criteria were articles before 2005 and nursing that was outside of bedside nursing or not acute care nursing. A total of 30 research articles were utilized and synthesized for this project.

Stress

Stress is conceptualized as an imbalance within many nursing theories and can be divided into two groups: eustress and distress (Riahl, 2011). These groups are a separation of a positive and negative influence of stress (O'Sullivan, 2011). Perception is a key component of understanding and neutralizing stress in an individual (Admi & Moshe-Eilon, 2010).

Perception. Each individual has a different perception of how stress is interpreted and when too much stress is dangerous to the individual's health (Admi &

Moshe-Eilon, 2010). Many factors can affect how someone reacts to and manages stressful events. Hardiness, personality, and individual coping mechanisms all have an influence on how stress is perceived and processed (Gibbons, Dempster, & Moutray, 2008).

Eustress. Eustress is a term used when stress has a positive response for the individual's well-being (Riahl, 2011). O'Sullivan (2011) defines eustress as "both the process of responding positively to stress as well as the positive outcome of this process" (p. 156). Studies indicate individuals with a small amount of stress are able to perform at optimal levels (Gibbons et al., 2008). O'Sullivan (2011) reports personal productivity and satisfaction is improved with the presence of eustress versus no stress. Ganz (2012) explores research that shows positive changes such as increased self-esteem, spiritual change, and enlightenment as a result of eustress. Eustress is desired to keep a person's health balanced on the stress continuum (Gibbons et al., 2008).

Distress. Distress can be referred to as stress that has a negative impact on an individual's health (O'Sullivan, 2011). Distress is a multifactorial event that produces both physiological and psychological detriment. Distress has been attributed to one of the leading causes to the destruction of nurses (Riahl, 2011). For the purpose of this project, stress will be associated with the definition of distress.

Contributing Factors to Stress in Nurses

Stress in nursing has been identified as a concern and explored through numerous research studies. Countless articles and studies have been explored to seek resolution of the stressors and the creation of healthy work environments for nurses (O'Sullivan, 2011). Admi and Moshe-Eilon (2010) reviewed 68 articles and cite workload, role

conflict, ambiguity, and lack of support as main origins of stress in working nurses (p.151).

Workload. The workload of a nurse has a multitude of components, but can be separated into two main components to include the work of direct patient care and the work of non-direct patient care (Buchan & Aiken, 2008). The nurse has the basic skill set that must be met within her/his scope of practice every day and they must hold a skill set that is a basic component of a typical employee. Direct and indirect workloads play a significant role in the stress felt by nurses (Myny et al., 2011).

Direct Patient Care. Nurses pride themselves on providing quality patient care. Increased direct patient care tasks and limited resources leave the nurse unsatisfied with job performances that increases stress and decreases work satisfaction (Riahl, 2011). Stress on nurses affect the quality of patient care that can increase deaths, complications, adverse events and length of hospital stays to patients (Ritter, 2010). Nosocomial infections are directly correlated to increase in the presence of an over stressed nurse (Purcell et al., 2011).

Non-Direct Patient Care. A number of non-direct activities increase stress in nurses. Healthcare organizations require nurses to do extra-curricular training and education to satisfy state and federal guidelines and organizational goals. Some states have mandatory continuing education credits due with recertification of licensure. Certification for special training such as cardiopulmonary resuscitation (CPR), advanced cardiovascular life support (ACLS), pediatric advanced life support (PALS), or other required department specific certifications are added to the above requirements. Charting

on care given to patients is one of the time consuming non-direct activities which adds to the nurses workload (Purcell et al., 2011).

Role Conflict. Patient care is a complex process (Brinkert, 2010). Nursing relies on effective interaction of interdisciplinary teams that requires a group of professionals to come together and provide a multiple specialty formulated plan of care. Brinkert (2010) states role conflict can be devastating to the plan of care for a patient and can lead to serious health consequences. Nosocomial infections are noted to increase with ineffective collaboration between interdisciplinary teams. Conflict between nursing and providers are among the number one reasons for medication errors (Purcell et al., 2011). Hsu et al. (2010) found that role conflict was the greatest predictor of occupational stress. Brinkert (2010) reports conflict and ineffective communication between the nurse and physician as one of the main sources of stress.

Role conflict is not only seen between health professionals and the nurse, but also between nursing colleagues. A high number of incidences related to violence, both physical and verbal, are noted between nursing coworkers. Conflict is seen on all levels of professional interaction when it refers to judgments on ethical matters or when addressing death and dying. Intergeneration conflict is a growing source of stress on both the nurse/patient and the nurse/colleague (Brinkert, 2010).

Ambiguity. Hsu et al. (2010) reports that it is essential for the nurse to have a clear understanding of the job description in order to achieve job satisfaction and quality patient care. Nurses frequently report on stress questionnaires feelings of uncertainty of a job description or what the expectations are from the nurse. Nearly one out of four nurses reported they had inadequate orientation to their current jobs. Improper

orientation to nursing roles and responsibility leads to confusion, frustration and inevitably poor patient care. Ambiguity often results in a perceived loss of control by the nurse. Unclear understanding of a job task can place nurses at risk for mistakes inside work place (Hsu et al., 2010).

Lack of Support. Nursing's focus is directed to the patient, but nurses require support as well. Many situations with patient care can exceed the nurse's physical and mental resources. It is essential to provide diligent support to the nurse in their work environment. Ineffective management style and leadership can cripple the nursing workforce (Admi & Moshe-Eilon, 2010). Lack of support from leadership increases stress to the nurse and decreases job satisfaction. This also increases emotional exhaustion, compassion fatigue and nurse burnout (Purcell et al., 2011).

Summary

Nurses are vulnerable to occupational stress (Riahl, 2011). Perception is important to factor when attempting to understand or ease occupational stressors. Multiple occupational stressors such as increased workloads, role conflicts, ambiguity, and lack of support are the main contributors of stress nurses are exposed to (Admi & Moshe-Eilon, 2010; Riahl, 2011). These stressors have a significant impact to the entire healthcare community.

Impact of Stress in Nurses

Riahl (2011) reports that stress on nurses have countless detrimental consequences and is the leading cause of nurses not practicing at their optimum levels. It affects the nurse's physically and mentally and has a direct negative impact on patient care (Riahl, 2011; Hsu et al., 2010). Purcell et al. (2011) found nurses in acute care

settings had reports of overwhelming stress and extreme exhaustion after their shifts. Stress is linked to hypertension, heart disease, heart rhythm disorders, gastrointestinal disease, neurological complications, immune disorders, sleep disorders and body weight problems. Mental illness links to stress are depression, anxiety, fatigue, hopelessness and uselessness (Ganz, 2012).

Nurses frequently attempt to self-medicate and develop inadequate coping skills like alcohol and substance abuse (Kunyk & Austin, 2012). According to Kunyk and Austin (2012), substance abuse is dangerously on the rise in nurses. They found 8.5% of nurses diagnosed with an alcohol addiction and two percent with a prescription medication addiction.

The impact of stress in nursing has reached a monumental financial burden on the economy (Riahl, 2011). Salmond and Ropis (2005) reported estimates from the Department of Health and Human Services that "stress has been estimated to cause half of workplace absenteeism and 40% of turnover, which is projected to cost the U.S. economy $200-$500 billion annually" (p.302). High nursing turnover rate, nursing shortage, burnout, and medical errors are all directly correlated to over stressed nurses (Riahl, 2011).

Loss of Nurses to the Workforce. The nursing shortage is a global concern for the healthcare communities (Hsu et al., 2010). Stress is not only a cause to the nursing shortage but it is also generating further stress to the under staffed nursing workforce (Purcell et al., 2011). Critical care nursing specifically has a shortage that causes concern on an international level. Nursing turnover, shortage, and burnout all have the similar origins correlating back to stress and workload (Mealer et al., 2012). Nearly 20% of

nurses are not able to leave work when their shifts are over (Purcell et al., 2011). Nurses frequently report ending a work day both mentally and physically exhausted (Riahl, 2010). Rotating shifts add increased stress to nurse's sleep quality, fatigue, and lack of recovery between shifts (Purcell et al., 2011). Burnout has been known to decrease self-esteem and exacerbate depression symptoms (Ganz, 2012).

According to Riahl (2011) the cost to replace a nurse can range from over $10,000 to nearly $70,000. One of four nurses has acknowledged feelings of burnout (Riahl, 2011). Hsu et al. (2010) found 43% of nurses who intended to leave the nursing profession reported high stress and burnout. Male nurse turnover rates are double the rate on average of their female counterparts, changing out of the nursing profession by the end of four years (Hsu et al., 2010). Buchan and Aiken (2008) stress that the shortage does not constitute a failure of qualified nurses, rather it reflects nurses who refuse to work under current work environments and stressors.

Medical Errors. Admi and Moshe-Eilon (2010) found that nurses who are over-worked have decreased ability for concentration and increased error record. Nurses who worked greater than 12.5 hours per day are more than three times likely to make a medical error. More than 30% of nurses admitted to medical errors and near misses while under stress (Purcell et al., 2011). Medical errors are contributed to nearly one hundred thousand patient deaths according to the IOM (Ritter, 2010). Medical errors have serious implications on the morbidity and mortality of the patient population. Stress is a known link to medical errors and medical errors cause stress, making occupational stress a vital issue to effectively manage (Karga et al., 2011).

Summary

The impact of occupational stress has damaging financial and health consequences to the nurse, patient and medical organization. Numerous mental and physical illnesses are reported in nurses under stress in their work environment (Ganz, 2012; Kunyk & Austin, 2012). The loss of nurses to the nursing shortage is directly related to nurses refusing to continue working in high stress environments (Buchan & Aiken, 2008). Medical errors increase significantly to patients under the care of an overly stressed nurse (Riahl, 2011). This impact is predicted to cost the medical industry billions of U.S. dollars but the impact is more serious than any dollar amount could represent (Riahl, 2011; Salmond & Ropis, 2005).

Clinical Practice Guidelines

The literature review provided adequate insight to multiple approaches of stress reduction in nursing and the creation of a healthy work environment. Stressors in nursing environments are found to be detrimental to the nurse, patient, and organization. Effective measures to reduce occupational stressors in nurses primarily relies on the creation of a healthy work environment that includes: 1) decreased workload, 2) decreased role conflict, 3) role clarity, and 4) increased support (Admi & Moshe-Eilon, 2010; Brinkert, 2010; Buchan & Aiken, 2008; Gibbons et al., 2008; Hsu et al., 2010; Myny et al., 2011; O'Sullivan, 2011; Purcell et al., 2011; Riahl, 2011).

Decreased Workload. An effective option to reduce stress in nursing is to decrease the amount of tasks nurses are responsible for. A reduction in nurse to patient ratio can reduce stress in nurses, increase in job satisfaction, and increase patient safety (Tellez, 2012). Frequent availability of charge nurses or clinical nurse specialist to assist

in nursing tasks can help allow the nurse to have uninterrupted breaks. Utilizing charge nurses and clinical nurse specialists can provide for nurses ease of mind when leaving patients to perform self-care for themselves by eating meals or taking a break from patient care (Riahl, 2011). The increase in availability of unlicensed medical personnel and nursing aides can help accomplish patient care tasks that are not nurse specific, therefore allowing more time for nurses to accomplish specific nurse only tasking's (Riahl, 2011; Tellez, 2012). Purcell et al. (2011) found planning was a frequent coping strategy for nurses to effectively manage their workday.

Decreased Role Conflict. Brinkert (2010) stated role conflict is a common occurrence within the healthcare teams but can be managed successfully with the proper tools. Good, effective communication is noted at the center of all conflict resolution programs. Improved communications between nurses and physicians have proven to decrease medication errors (Ritter, 2010). Programs that provide a mentor program have helped to reduce the role conflicts between new and seasoned nurses. Mentor programs offer a reduction of stress with increased camaraderie between the nursing staff and increases colleague support. Conflict management workshops show positive impacts on nurses attending mandatory training and reported benefits at three months post training. Conflict among nursing can be welcomed in the right circumstances and with mutual respect for each party involved (Brinkert 2010; Riahl, 2010).

Role Clarity. Role definition and job description play a vital role in stress reduction of nurses. Brinkert (2010) found the use of protocols in hospital units drastically decreased miscommunication between the nurse and adjunct faculty and improved clarity of roles in nursing. Riahl (2011) notes that feedback from leadership

which included constructive criticism allowed for better understanding of job performance and improved satisfaction of their work environment. Proper orientation to a nurses work center provides the nurse with a sense of control, understanding of expectations, role definition, and enhances patient safety (Hsu et al, 2010). According to Riahl (2011) nurses stated a perceived sense of control allowed for a lowered level of stress in greater satisfaction in their work.

Increased Support. Riahl (2011) found leadership recognition to nurses for job performance and accomplishments provided a reduction in reported occupational stress. Riahl also notes that a transformational leadership style was appreciated and allowed for nurses to grow and work together with their leadership to promote their nursing career (Riahl, 2011). Transformational leadership allows a mutual respect between nurses and leadership, sense of empowerment, and mutual motivation to achieve a sense of pride and satisfaction in their performance and mission (Grossman & Valiga, 2009). Nurses with increased peer support and encouragement had lower levels of stress, decreased incidences in medical mistakes, improved job performances, and satisfaction in their work environment (Riahl, 2011). Admi and Moshe-Eilon (2010) recommend programs focused on teamwork to provide peer support, healthy coping methods, and safe expressions of frustrations.

Summary

Research provides a clear understanding of several factors affecting occupational stress in nursing and various ways to help create healthy work environments. Decreased workload, decreased role conflict, role clarity and increased support all serve an important factor in improving the work environment and reducing stress in nurses (Riahl,

2011). A healthy work environment has become the focus to generate excellence in nursing as supported by American Association of Critical-Care Nurses, Joint Commission for Accreditation of Hospitals, IOM, American Nurses Credentialing Center, American Organization of Nurse Executives, American Association of Colleges of Nursing, and Nursing Organizations Alliance (Kramer & Schmalenberg, 2008).

Implementing scheduled meal breaks attempted to address the above clinical practice guidelines recommendations to reduce stress in the nurse and create a healthy work environment. The creation of scheduled meal breaks with the use of break buddies provided a system to aid in a decreased workload by providing a partner for sharing tasks during the shift while ensuring a trusted partner to care for patients. The break buddy system to ensure a schedule meal break sought to decrease role conflict by building camaraderie. Providing a scheduled system to ensure meal breaks intended to clarify the role of the nurse in patient care by emphasizing the importance of self-care. Ensuring self-care practices as priority was intended to promote self-esteem, self-worth, job satisfaction, and quality patient care. Increased support was intended by leadership approving and ensuring formal policies to safeguard scheduled meal breaks and self-care to their nurses. Scheduled meal breaks projected to allow for the nurse to increase numerous coping mechanisms against occupational stress and the creation of a healthy work environment (Kramer & Schmalenberg, 2008).

Gaps

Literature available is abundant on the topic of stress in nursing and the creation of a healthy work environment. Research related to critical care nursing focuses frequently on the mental and emotional stress that comes with taking care of the critically

ill patients and the aftermath of post-traumatic stress disorder, depression, and burnout (Mealer et al., 2012). Infrequently a piece of literature addresses the impact a meal break has on the nurse. Paris and Terhaar (2011) identified this area was a concern when they started reviewing scores from their results of the National Database of Nursing Quality Indicators (NDNQI). The use of this knowledge provided for the development of a performance improvement project that showed great improvement in this area for their facility. Stefancyk (2009) successfully implemented one hour off the unit breaks to ease the stress of bedside nursing during their initiative to transforming care at the bedside. Few performance improvement projects have been published on the topic to add to the body of evidenced based practice (Paris & Terhaar, 2011; Stefancyk, 2009).

Evidence Based Practice Model

The project was guided by the Iowa Model of Evidenced-Based Practice to Promote Quality Care. This model is frequently used throughout nursing research and has proven to add quality research to the healthcare community (Melnyk, & Fineout-Overholt, 2011). The facility where the PIP was implemented utilizes this model in their research programs (Figure 3).

The Iowa model is an effective approach for medical leaders to systematically promote and implement evidenced based research into their medical communities to improve quality of care. This model provided a logical step by step approach with feedback loops for revisions. The first step of the model identified an area for improvement that was a problem focused trigger and a knowledge focus trigger. The next step ensured the PIP was a priority for the organization and a team was formulated.

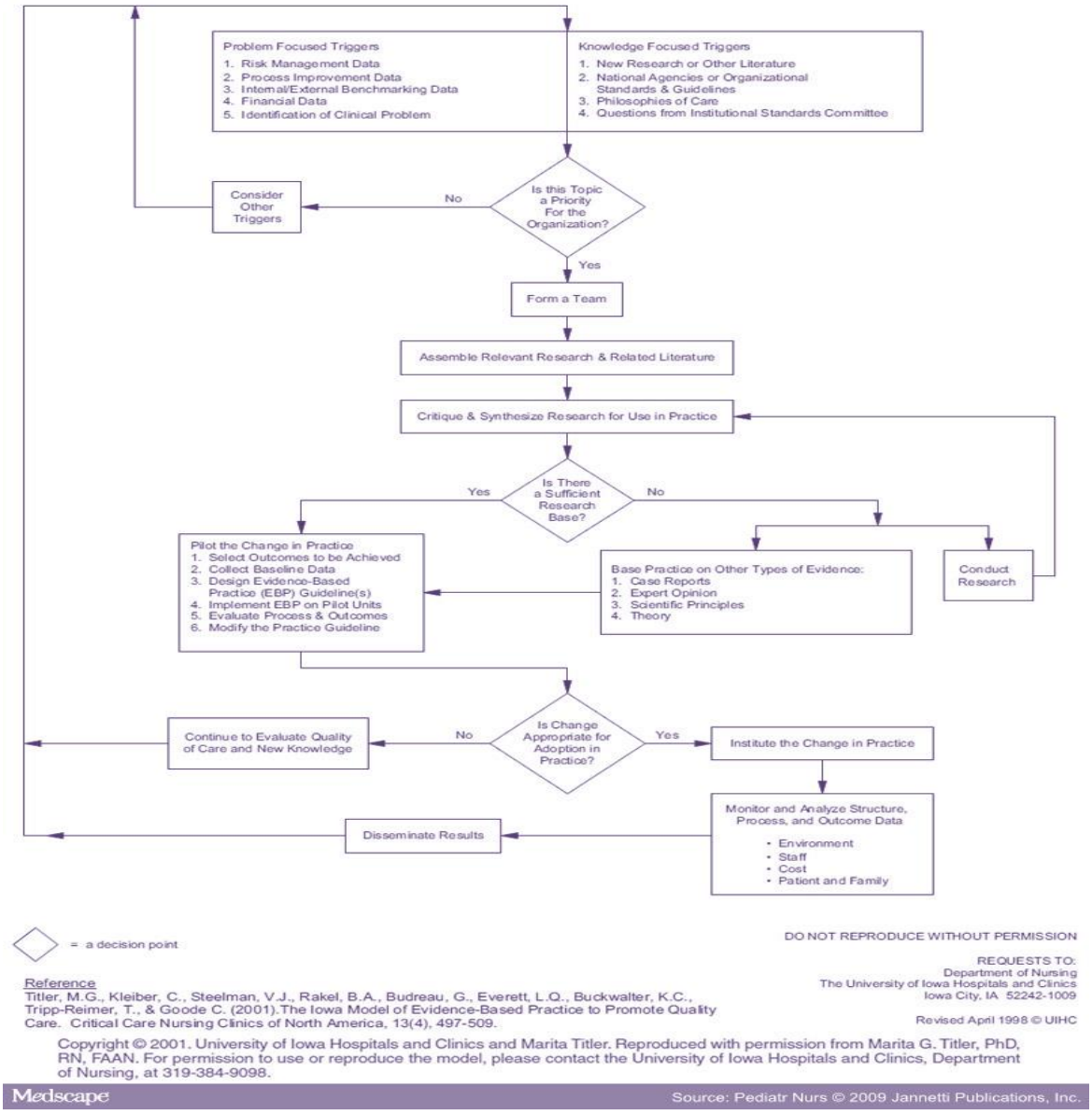
A relationship was developed with the stakeholders and feedback was requested from the education committee to further develop the idea of the scheduled meal breaks. The team consists of the DNP student, facility Director of Nursing (DON), ICU director and assistant directors, and education council for the ICU. The formation of the team continued the models direction and relevant research and literature was shared with the team over three months to critique and synthesize.

The next step in the model was for the team to determine if there was literature supportive of the proposed change in practice. There was a unanimous vote to move forward. The identified outcome to be achieved was improved access to meal breaks. Collection of baseline data was done by a pre-survey prior to education or implementation of the project. Implementation allowed for evaluation and modification of practice guidelines after the post-survey was collected and data was statistically analyzed.

The change was predicated to show improvement to practice and recommendation were made that the change is appropriate for adoption of practice which satisfied the next step of the module. The adoption of the change into practice provided the opportunity to monitor and analyze the new change to ensure successful change. Ensuring successful change will provide for the last step of the model, the dissemination of the results.

Figure 2

Iowa Model of Evidence-Based Practice to Promote Quality Care. Retrieved from http://www.medscape.com/viewarticle/489955_2



Nursing Theory

The nursing theory which guided this project was Dorthea Orem's Self-Care Deficit Nursing Theory (SCDNT). SCDNT was developed as a grand theory. The grand

theory is a generalized theory that incorporates three smaller theories: theory of self-care, theory of self-care deficit, and the theory of nursing system (Parker & Smith, 2010, p.125).

The theory of self-care describes the individual with mental and physical capabilities to ensure actions are completed to care for oneself with promotion of health and life sustaining activities (Parker & Smith, 2010). The PIP population represented college graduates with a degree in nursing. The importance of the self-care knowledge and ability of self-care was evident within this population's educational background and training. The PIP population proved competency in their ability to educate and promote self-care task for their patient population, but frequently ignored their personal need for self-care during work hours (A. Mills, personal communication, April 28, 20014; R. Haxton, personal communication, May 27, 2014).

The theory of self-care deficit is when the patient, the ICU nurse for this project, has lost the ability to care for themselves and needs to engage in a nursing intervention. The self-care deficit identified was missed meal breaks or inadequate meal breaks. The PIP population had not lost the ability to care for themselves personally, but needed a nursing intervention to remind them of the importance of a meal break. This also provided a formal plan to support them through this process. The PIP provided an intervention to follow the SCDNT that provided information with evidence based literature about the creation of a healthy work environment and the negative consequences of stress in nurses and impact of missed meal breaks.

The theory of nursing system engages when the relationship between nurse and patient begin an interpersonal relationship (Parker & Smith, 2010). The project provided

guidance and nursing care to and from the nurses with use of the meal break buddy and encouragement from charge nurses and leadership. This allowed for a teamwork approach by using the nursing process. The SCDNT theory was a good fit for this project as it allowed nurses to nurture other nurses. Orem's theory provided a creative way to integrate both of these systems.

Change Theory

The change theory incorporated in this project was the Lewin's Change Theory (LCT). The PIP project implemented a change with scheduled meal breaks. The LCT provided an organized flow that aided with the facilitation the change of culture in this PIP population. Grant, Colello, Riehle, and Dende, (2010) report LCT focuses on the three phases of change: unfreezing, moving, and refreezing.

The unfreezing stage allowed for identification and awareness of the problem and preparation to the agent for change. The moving phase supported and encouraged the individuals through the change process and planned for effective ways to manage resistance. The refreezing stage involved ensuring the change had stabilized and formulated procedures to keep the new change effective (Marquis & Huston, 2009).

The unfreezing phase provided the opportunity for the DNP student to have a conversation with the stakeholder and unit director to identify a change needed within the unit. Identification for change was the lack of effective meal breaks in the critical care unit nurses and awareness of resistance from these nurses on a program to assist with ensuring effective meal breaks. The next step was a survey of the critical care nurse's knowledge on meal breaks. A pre-survey was given to the unit nurses before introducing the scheduled meal break intervention. After the completion of the pre-tests, an email

informing the ICU nurses of the consequences to ineffective meal breaks and details of the scheduled meal break initiative was sent to them by the ICU unit secretary. The DNP student spent one week rounding through all ICU units on day and night shifts educating staff on the meal break initiative and discussing evidenced based practice behind the change. Posters were hung in each unit to reinforce how and why the changes were taking place and encourage participation.

The moving phase solidified commitment to the change and provided support and resources during the phase (Marquis & Huston, 2009). Implementation is detailed below.

- Unit representative nurses assisted ICU nurses to choose a break buddy during the process of shift change.
- After the break buddy was declared, the nurse worked with the nurse team to declare meal break times and ensure proper coverage for all patients during these breaks.
- The nurse reported their patient assignment along with time desired for meal break to the health unit clerk (HUC) to be documented on meal break check sheets and reported to the charge nurse during rounding.
- The charge nurses, assistant directors, and director rounded daily to encourage and evaluate if break buddies were being declared and if meal breaks were being achieved.

A four week time frame was given to allow time for implementation. Close contact was maintained with leadership and support staff to ensure no roadblocks prevented the PIP from success. There was no contact with floor nurses in the ICU at that time.

The freezing phase is intended to solidify change and document successful procedures to ensure change remains in use. Effective change will need three to six months before change can be evident (Marquis & Huston, 2009). This project is intended to change a culture and will need a longer period of unfreezing and moving before freezing can be declared.

Chapter 3: Project Design and Methodology

Introduction

This chapter discusses the project design and methodology. Population, design, setting, sampling criteria, procedures, stakeholders, barriers, facilitators and interventions are detailed. Protection of human subjects, anticipated outcomes and data analysis are discussed.

Population, Study Design, and Setting

The study took place at a trauma level II, 329 inpatient bed hospital located in a city of 65,000 in a Midwestern state. A quasi-experimental design was used to determine what impact scheduled meal breaks have on the work environment for ICU nurses. The quasi-experimental design was chosen since the nursing staff could not be randomized and it was not possible to control every variable in the project (Bunurses & Grove, 2009). The sample consisted of 93 nurses who work in four ICU units of this hospital. This number represented 73 full-time, 14 part-time and six per diem nurses employed in the ICUs. The nurses are predominantly Caucasian and female.

Sampling Criteria

A convenience sample was utilized. Survey participation was requested from all nurses assigned to the ICU in this hospital. The ICU is comprised of four units; surgical ICU, medical ICU, coronary care ICU, and transitional ICU. The four units can admit up to 33 patients. The units average a 78% bed occupation on census (A. Mills, personal communication, September 19, 2014).

Instruments

The survey used was the Meal Break Impact Survey (MBIS) in this study (Appendix A). A search of the literature did not identify a validated tool that would meet the needs of this PIP. The MBIS was developed to capture specific data around meal breaks and nurses. Questions were formulated to assess availability, length, quality, satisfaction, performance and stress levels in relation to their meal break. The questions were formulated based on data found in the literature review. The MBIS was reviewed and revised by four doctoral prepared faculty members at South Dakota State University (SDSU) with a background in ICU nursing and the stakeholder who holds a doctorate in nursing practice. The MBIS was presented to these five experts who provided content validity.

The MBIS is a 19-item questionnaire utilizing Likert scale responses. The MBIS has five demographic questions. Fourteen questions ask about availability, length, quality, satisfaction, performance and stress levels in relation to their meal break. Six questions ask respondents to mark the categories of strongly agree, agree, neutral, disagree, and strongly disagree. Eight questions require responses of 100% of the time, 75% of the time, 50% of the time, 25% of the time, and 0% of the time.

Study Procedure

The project took place in four phases. In the initial phase all ICU nurses were requested to anonymously fill out the MBIS via Survey Monkey©. This was sent by the unit secretary through work email to gather baseline data and produce a pre-intervention survey. Surveys were also distributed in paper form to ICU nurses by the charge nurses and unit secretary. The paper surveys were collected, scanned into the computer, and

emailed to the DNP student by the unit secretary. The surveys were entered into Survey Monkey©. A two week time frame was allotted to collect the data from pre-intervention surveys.

The second phase included an email to the ICU nurses explaining the new implementation of scheduled meal breaks and evidenced-based research behind the PIP. Rounding in the ICU occurred over a week alternating day and night shifts to educate ICU nurses on the intervention. Posters with this information were hung in each unit. The education part lasted for one week.

The third phase was the intervention. The unit nurse representative, the nurse who represents a specific unit, was in charge of ensuring each nurse identified a break buddy during shift change report. The nurses were asked to work together to identify their declared meal beak time ensuring coverage for the floor before the end of shift change report. The nurse was asked to report their patient assignment along with time desired for meal break to the HUC to be documented on the meal break check sheet and reported to the charge nurse when rounding.

The charge nurse was asked to take the meal break check sheets to the unit secretary to keep data for DNP student. The charge nurses, assistant directors, and director rounded daily to evaluate if nurses were being assigned a break buddy, declaring a time desired for meal breaks, and taking meal breaks. They also provided encouragement and assurance during this time. No reprimand occurred if break buddies or breaks were not achieved. The declared break schedule was implemented for four weeks.

The last phase resurveyed the ICU nurses via Survey Monkey©. Surveys were sent by the unit secretary to the personal work email of the ICU nurse. Surveys were also distributed in paper form for completion of nurses. The paper surveys were scanned then emailed to the DNP student by the unit secretary. The DNP student manually entered them into Survey Monkey©. A two week time frame was given to collect post-intervention data.

Stakeholder Support

The DON and the director of ICU were in support and approved the PIP. The Education Council for ICU was also supportive of this project. The Innovation Council for the hospital reviewed and supported this project.

Barriers and Facilitators

Challenges expected and encountered were the workload of the nurse and resistance of the ICU nurses for change of the culture. The ICU has an increased workload that poses a challenge to plan or organize the nurse's day. Workload was a barrier for nurses to get a break despite the use of a break buddy or declared meal break time. Some of the ICU nurses were barriers to the success of the project. A few ICU nurses did not agree with having someone encourage scheduled lunches for them and were vocal in their disagreement to the DNP student and nursing leadership for the ICU. Lack of education on the topic of the break initiative was also a barrier to the project. Education was completed by rounding with the ICU nurses and through work email. ICU nurses where asked while rounding if they read the education and literature. Only a few nurses stated they were able to find time to review the education that was emailed. Education was attempted during rounding while nurses were on shift. Uninterrupted time

to discuss the evidence behind the meal break initiative was not available. Attention to dissemination of the research evidence and education was important to having the nurses embrace the project.

Facilitators included the DNP student and the student's PIP committee. The PIP committee provided guidance, support, and direction through the entire project. The DNP student gathered the evidence, formulated the program, implemented and formulated findings of the program. The DON and ICU director were also key facilitators.

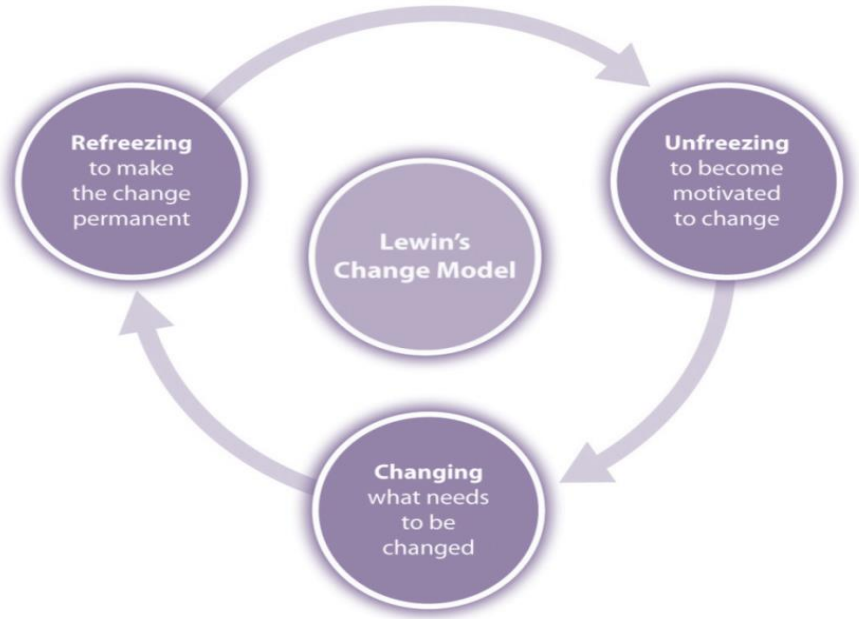
Protection of Human Subjects

This project was submitted to the Internal Review Board (IRB) at SDSU and the hospital where the project is implemented and was determined exempt from IRB approval. Surveys were completed anonymously.

Change Theory

Lewin's Change Theory (LCT) guided this project (Figure 5). Grant et al. (2010) report LCT focuses on the three phases of change: unfreezing, moving, and refreezing. The unfreezing phase was devoted to educating staff on the main focus and expectations of the program. The unfreezing phase incorporated time to provide positive information and solid evidence about the change. It was important in the unfreezing phrase to listen to input and gain feedback from the staff. The moving phase solidifies commitment to the change and provides support and resources during the phase. The freezing phase has not been accomplished at this time. Time will be needed for continued support for a continuation of the unfreezing and moving phases before freezing can be declared (Grant et al., 2010).

Figure 3. Lewin's Change Model



Anticipated Outcomes

Anticipated outcomes included: 1) increased planning to ensure time to take meal breaks, 2) increased meal breaks taken, and 3) decreased shifts that have no meal breaks declared among ICU nurses.

Data Analysis

The demographic data, hospital data, and meal break check sheets were analyzed and are reported in frequencies and percentages. The pre and post-survey items on the MBIS were analyzed using a t-test with a significance level of $p < 0.05$.

Summary

The project was completed in an ICU unit of a hospital in a Midwestern state. This unit employed 93 ICU nurses. The project was designed to help ICU nurses plan for

successful meal breaks and to improve their work environment. Stakeholder support was important to gain facilitators and overcome barriers.

Chapter 4: Outcomes & Impact of Practice Innovation Project

Introduction

This chapter discusses the outcomes and impact of the PIP. The demographics of the participants are discussed and the statistical analysis reported.

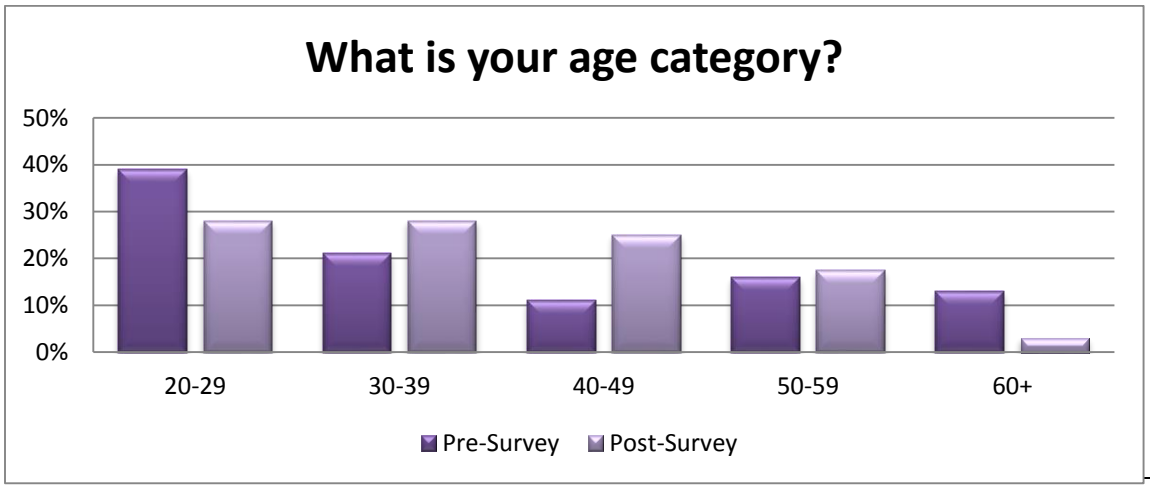
Demographic Data

The study took place at an inpatient hospital located in a Midwestern state. The sample consisted of 93 nurses who work in four ICU units of this hospital. This number represented 73 full-time, 14 part-time and six per diem nurses employed in the ICUs. Data analysis was completed on 38 pre-surveys and 36 post- surveys.

The respondents in the pre-survey ranged in age from 20 to 60+ years of age. The nurses were grouped into categories and 15 (39%) were in the 20-29 age range. Eight respondents (21%) were in the 30-39 age range category and 4 (11%) were in the 40-49 year range. Six respondents (16%) fell in the 50-59 year level and five (13%) were over the age of 60. In the post-survey group 10 (28%) were in the 20-29 age range, 10 (28%) were in the 30-39 age range, and nine (25%) were in the 40-49 age range. A smaller number six (17%) fell in the 50-59 age range and one (3%) were over the age of 60 (see Table 2).

Table 2

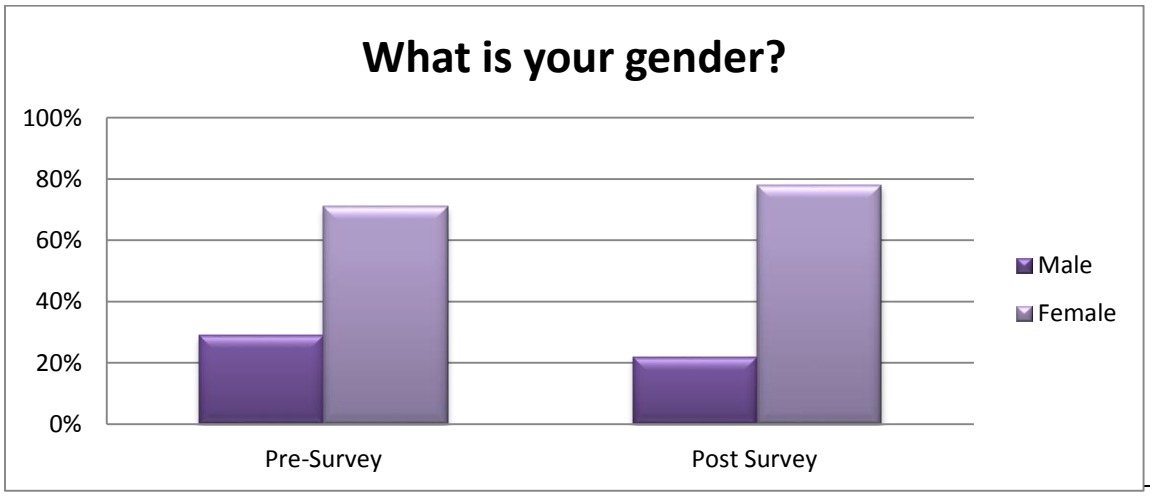
Age Category



Respondents were asked to identify themselves as male or female gendered. The pre-survey group found 27 (71%) to be female and 11 (29%) to be male. In the post-survey group, 28 (78%) were female and eight (22%) were male (see Table 3).

Table 3

Gender

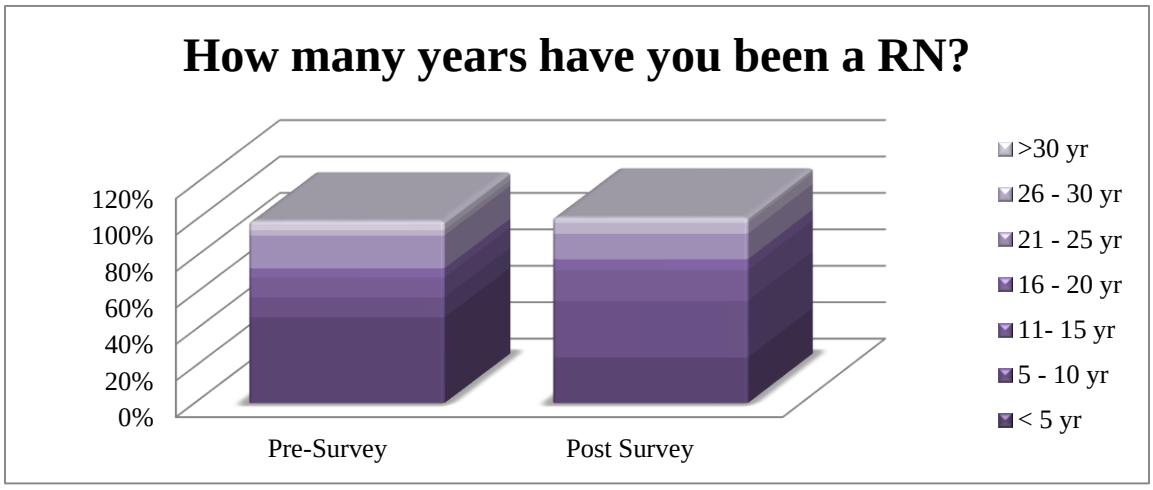


The respondents in the pre-survey question years as a RN ranged from 0 to > 30 years. Nurses in the pre-survey group were 18 (47%) in the less five years group, four (11%) in the 5-10 year group, and four (11%) in the 11–15 year group. A smaller representative was found with two (5%) in the 16-20 year group, seven (18%) in the 21-25 year group, one (3%) in the 26-30 year group, and two (5%) in the >30 year group (see Table 4).

The post-survey had nine (25%) nurses in the under 5 year group, 11 (31%) in the 5-10 year group, and six (17%) in the 11–15 year group. In the 16-20 year group, two (6%) nurses, five (14%) in the 21-25 year group, two (6%) in the 26-30 year group, and one (3%) in the >30 year group (see Table 4).

Table 4

Years as a RN



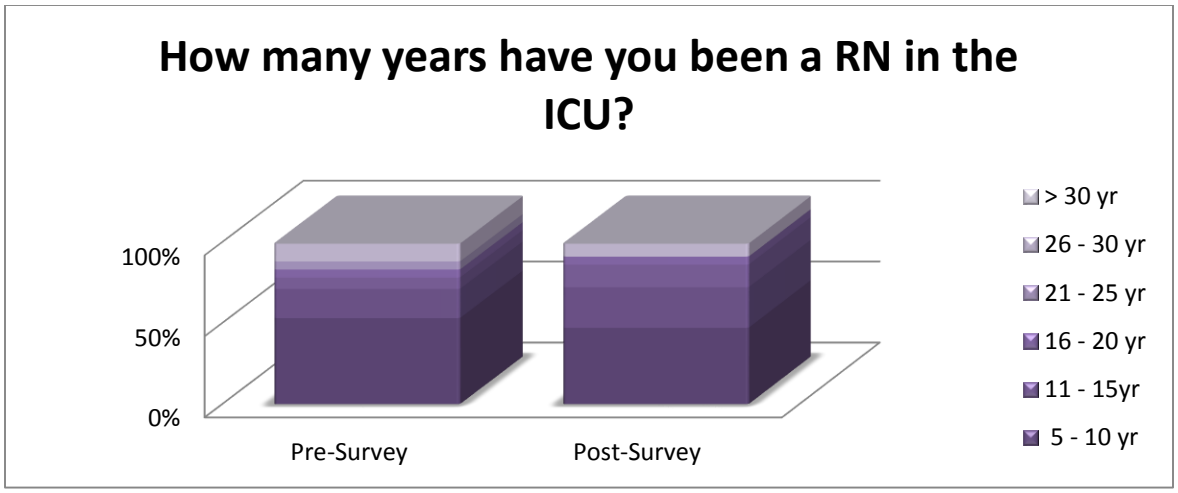
The respondents in the pre-survey ranged in years as an ICU RN from 0 to > 30 years. There were 20 (53%) in the pre-survey group in the less than five years group, seven (18%) in the 5-10 year group, and three (7%) in the 11–15 year group. ICU nurses

in the 16-20 year group had two (5%), two (5%) in the 21-25 year group, four (11%) in the 26-30 year group, and zero in the >30 year group.

ICU nurses in the post-survey group were 17 (47%) in the less than five years group, nine (25%) in the 5-10 year group, and five (14%) in the 11–15 year group. The 16-20 year group had two (5%), zero in the 21-25 year group, three (8%) in the 26-30 year group, and zero in the >30 year group (see Table 5).

Table 5

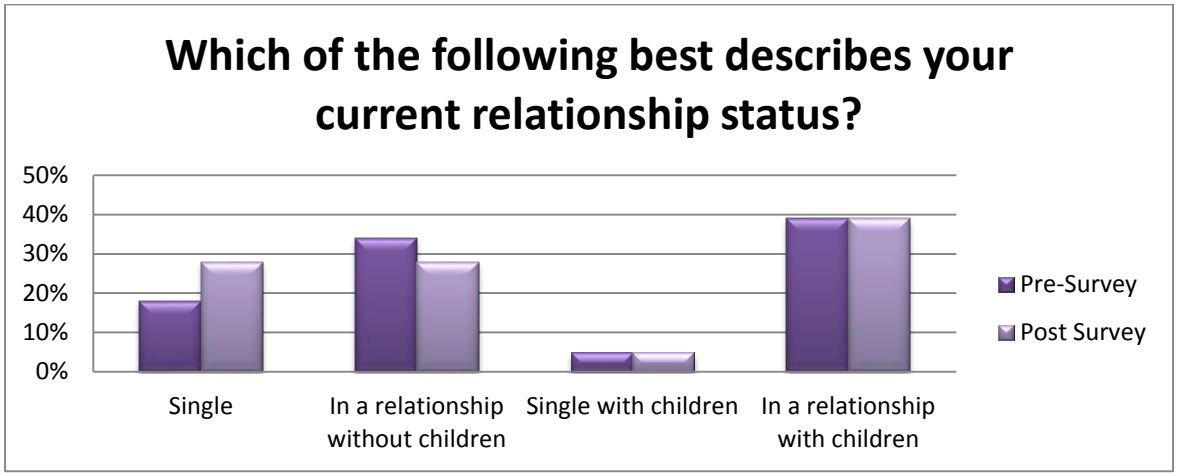
Years as a RN in the ICU



The respondents in the pre-survey were asked to identify between four different relationship categories. Seven (18%) of respondents identified as single, 13 (34%) in a relationship without children, two (5%) single with children, and 15 (39%) in a relationship with children. In the post-survey group, 10 (28%) identified as single, 10 (28%) in a relationship without children, two (5%) single with children, and 14 (39%) in a relationship with children (see Table 6).

Table 6

Relationship status



Data Analysis

Pre and post intervention data from the MBIS were examined. Pre and post-surveys were sent to 93 nurses in the ICU. There were 49 pre-surveys and 46 post-surveys returned. Two surveys from the pre-survey data and one survey from the post-survey data were removed because only demographical data was completed. Nine surveys matched all five demographical questions on pre and post-surveys and were discarded from data analysis to eliminate potential bias due to likeness in response and to provide two totally independent samples. Final pre-survey data included 38 surveys and post-survey data included 36 surveys.

A t-test for independent samples was performed to measure the means of pre-survey and post-survey. The calculated probability level of $p < 0.05$ was utilized to test for statistical significance. A two-tailed p value was utilized since it was unclear which direction a difference may have occurred.

Four questions were reversed coded since they are negatively worded. These questions included 1) question 7 - *I am satisfied with the care I provide my patients when I am not able to take a meal break,* 2) question 10 - *Taking a meal break increases my stress level during my shift,* 3) question 14 - *How often is your meal breaks interrupted because you must return to patient care* and 4) question 15 - *How often do you not take a meal break because there is no one to relieve you?*.

The t-test was completed on the average score from pre versus post-survey. No statistical significance was found between the pre versus post-survey. The t-test was completed on individual questions between pre versus post-surveys. Question number 19, *I am satisfied with my ability to take a meal break during work* was found to be statically significant at a $p < 0.05$ level (see Table 7).

Table 7

MBIS Survey Analysis

Variables	n	df	Mean	Variance	Standard Deviation	*p*-value two tail
Total: Pre-survey	522		2.871	1.666	1.290	
Total: Post-survey	501		2.776	1.529	1.237	
		1021				0.228
Q.6 Meal breaks are important to me.						
Pre-survey	38		1.605	0.623	0.789	
Post-survey	36		1.722	0.492	0.701	
		72		0.251	0.502	0.502
Q.7 I am satisfied with the care I provide my patients when I am not able to take a meal break						
Pre-survey	37		2.946	0.941	0.970	

Post-survey	36		2.944	1.482	1.217	
		67				0.995
Q.8 I am more satisfied with my job when I am able to take a meal break.						
Pre-survey	38		1.447	0.416	0.645	
Post-survey	36		1.639	0.580	0.762	
		69				0.248
Q.9 Knowing when my meal break is reduces my stress for the shift.						
Pre Survey	37		2.568	0.808	0.899	
Post-survey	35		2.742	1.196	1.094	
		66				0.461
Q.10 Taking a meal break increases my stress level during my shift.						
Pre-survey	38		2.526	1.337	1.156	
Post-survey	36		2.361	1.094	1.046	
		72				0.521
Q.11 I feel more alert and refreshed when I am able to take a meal break.						
Pre-survey	38		1.553	0.524	0.724	
Post-survey	36		1.639	0.637	0.798	
		70				0.628
Q.12 I have a plan for ensuring time to take my meal break within my shift.						
Pre-survey	37		3.324	1.891	1.375	
Post-survey	36		3.139	1.437	1.199	
		70				0.541
Q.13 When my shift begins, there is a plan to ensure all staff is able to take a break.						
Pre-survey	38		3.947	1.619	1.272	
Post-survey	36		3.801	1.190	1.091	
		71				0.607
Q.14 How often is your meal breaks interrupted because you must return to patient care?						
Pre-survey	36		3.111	1.016	1.008	
Post-survey	35		2.714	1.034	1.017	
		69				0.103

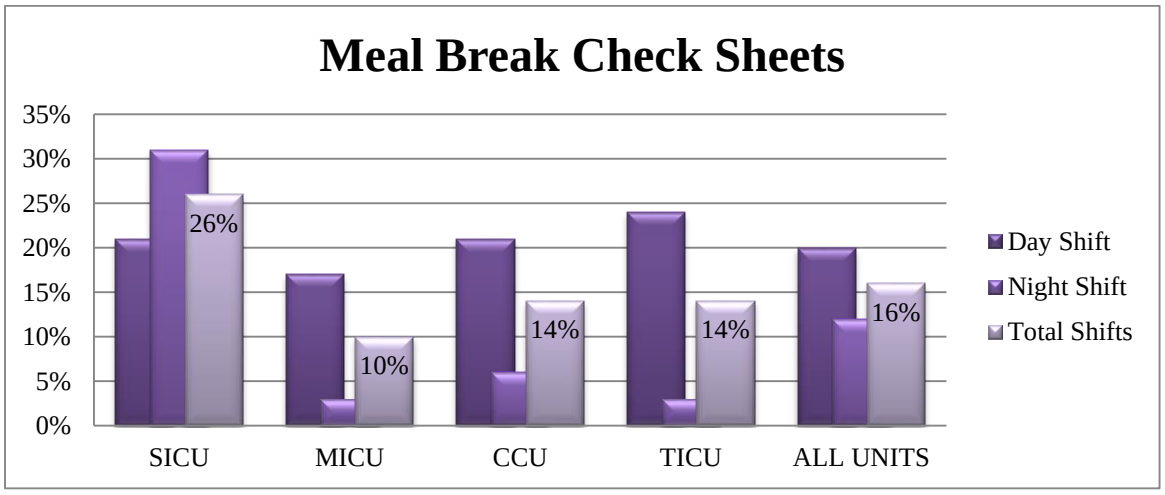
Q.15 How often do you not take a meal break because there is no one to relieve you?						
Pre-survey	36		2.972	1.284	1.133	
Post-survey	36		2.806	1.304	1.141	
		70				0.536
Q.16 I am able to take a meal break each shift I work.						
Pre-survey	37		3.081	0.910	0.954	
Post-survey	36		3.25	1.050	1.025	
		70				0.469
Q.17 I am able to take a meal break within the first half of my shift.						
Pre-survey	38		3.974	0.621	0.788	
Post-survey	35		3.829	1.264	1.124	
		60				0.529
Q.18 I am able to take 30 minutes for a meal break.						
Pre-survey	37		3.541	1.033	1.016	
Post-survey	36		3.194	1.247	1.117	
		70				0.171
Q.19 I am satisfied with my ability to take a meal break during work.						
Pre-survey	37		3.676	1.170	1.082	
Post-survey	36		3.111	1.073	1.036	
		71				0.026

Check Sheets. Meal break check sheets were used to document declared break buddies and declared break times during shift change report by the ICU nurses. Charge nurses utilized these sheets when they rounded between units to validate the ICU nurses identified break buddies and times. The check sheets allowed the charge nurses to see if nurses where planning their meal breaks and offer guidance or assistance to ensure break times where received and successful. During the intervention period, 16% (37) of the shifts worked completed the meal break check sheet.

Meal break check sheets were divided by units and day or night shift. Check sheets completed from the SICU consisted of six (21%) for the day shift and nine (31%) for the night shift. This resulted in 15 (26%) completed for all of the SICU shifts in the study. The MICU had five (17%) completed check sheets for the day shift and one (3%) for night shift. This resulted in six (10%) completed for all of the MICU shifts in the study. CCU completed six (21%) of the day shift check sheets and two (6%) check sheets. This resulted in eight (14%) for all the CCU shifts in the study. Completed check sheets for the TICU day shift were seven (24%) for the day shift and one (3%) for the night shift. This resulted in eight (14%) completed for all of the TICU shifts in the study. The total of day shifts completed sheets for all four units were 23 (20%) of the day shifts and 14 (12%) of the night shifts. This totaled 37 (16%) completed meal break check sheets for total for all units (see Table 8).

Table 8

Meal break check sheets

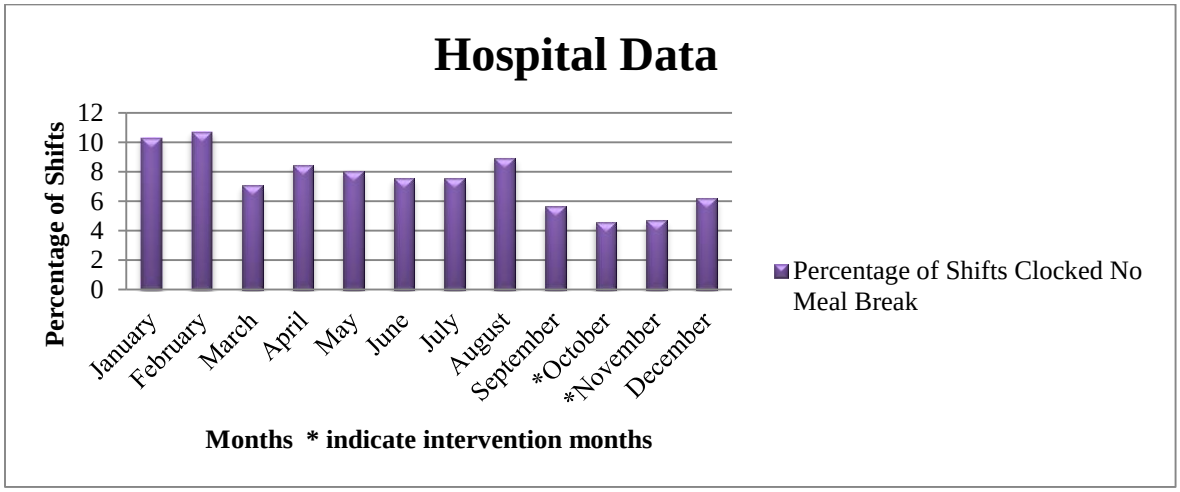


From January through September 2014, nurses in the ICU reported taking no meal breaks, by clocking in *no meal breaks,* on average 8.25% of the time. During October and

November 2014 when the intervention was taking place, nurses in the ICU reported taking no meal breaks on average 4.65% of the time. Many variables could have affected the percentages of the clocked no meal breaks (Table 1b).

Table 1b

Clocked no meal break for ICU Nurses at PIP location



Comments from Surveys

Staff provided verbal feedback during educational rounding that they appreciated the attention and awareness of the importance of meal breaks brought by the program. Feedback from post surveys included remarks that stated it helped with awareness. Eight surveys were returned with hand written remarks. Five of the remarks stated the initiative helped with awareness to meal breaks. A few remarks were “This has increased awareness of planning for meals”, “Our team's willingness to plan for meals and take care of each other has increased due to this initiative”, and “It has helped with awareness of the lack of breaks”. Two of the responses indicated a lack of comfort in leaving ICU

patients with inexperienced nurses, and one stated they wished nurses would have been more positive about the change.

Discussion

The demographic findings are consistent with the majority of the members currently in the ICU where the program took place. This was validated as an adequate representation of the ICU staff by the stakeholder (N. Zoll, personal communication, January 8, 2014). Statistical significance of a $p < 0.05$ was found with one question on the MBIS that shows the program helped to improve satisfaction of the nurses ability to take a meal break during lunch. Average clocked no meal breaks by ICU nurses were found to decrease during the intervention months. Feedback on post-surveys indicated increased awareness of needed meal breaks. The projects demographic data indicates a true representation of the population of the PIP and showed improvements in satisfaction, increased meal breaks, and awareness.

Ultimate impact

The PIP served as method to open a conversation about meal breaks and trial a potential solution for ICU nurses. The PIP offered an opportunity to explore potential barriers and facilitators to the solution of meal break. Knowledge was collected through the PIP to help the facility take the next step to improve the work environment.

Chapter 5: Summary

Introduction

This chapter includes the summary and conclusion of the PIP. Reflection on the successes and areas for improvement are discussed. Recommendations for future studies are made.

Summary

The purpose of the study sought to explore the impact of meal breaks on ICU nurses when nurses are able to schedule meal breaks at the beginning of their shifts during shift change report. The objective was to improve nurse's access to receive a 30 minutes meal break with their worked shift. The PICOT question offered an evidenced based focus to implement a system for ICU nurses to schedule meal breaks in an attempt to support a healthy work environment and lighten stressors. This project sought to answer the following question: *In ICU nurses, what is the impact of scheduled meal breaks compared to nurses who didn't have scheduled meal breaks over four weeks.*

The literature review found nurses, especially ICU nurses, are vulnerable to occupational stress (Mealer, Jones, & Moss, 2012; Purcell et al., 2011; Riahl, 2011). Multiple occupational stressors such as increased workloads, role conflicts, ambiguity, and lack of support are the main contributors of stress nurses are exposed to (Admi & Moshe-Eilon, 2010; Riahl, 2011). The loss of nurses to the nursing shortage is directly related to nurses refusing to continue working in high stress environments (Buchan & Aiken, 2008).

Decreased workload, decreased role conflict, role clarity and increased support all serve as important factors in improving the work environment and reducing stress in nurses (Riahl, 2011). A healthy work environment has become the focus to generate excellence in nursing as supported by American Association of Critical-Care Nurses, Joint Commission for Accreditation of Hospitals, Institute of Medicine, American Nurses Credentialing Center, American Organization of Nurse Executives, American Association of Colleges of Nursing, and Nursing Organizations Alliance (Kramer & Schmalenberg, 2008).

The project was guided by the Iowa Model of Evidenced-Based Practice to Promote Quality Care. The nursing theory which guided this project was Dorthea Orem's SCDNT. The change theory incorporated in this project was the Lewin's Change Theory (LCT).

The project was conducted in an ICU unit of a Midwestern state. Ninety-three ICU nurses represent this unit. The project was designed to help ICU nurses plan for successful meal breaks and to improve their work environment. Stakeholder support was important to gain facilitators and overcome barriers.

A t-test for independent samples was performed to measure the means of pre-survey and post-survey responses. The t-test was completed on the average score from pre versus post-surveys. No statistical significance was found between the pre and post-survey. The t-test was completed on individual questions between pre versus post-surveys. Question number 19, *I am satisfied with my ability to take a meal break during work* was statically significant at a $p < 0.05$ level.

Additional findings that impact the project are ICU nurses averaged 8.25% clocked no meal break from January through September 2014. This number decreased to an average of 4.65% during the intervention months of October and November 2014.

Limitations

This study had several limitations. First, this study used a convenience sample in one Midwestern hospital. Out of the 93 nurses, 41% of the participants completed the pre-survey and 39% completed the post-survey. These nurses may or may not be reflective of other ICUs. Second, the pre and post-surveys were not paired. Providing surveys with an identifier would have allowed for pre and post-surveys to be paired and provided better reflection of the impact of the intervention.

Third, resistance from staff was observed in rounding, reports from charge nurses, reports from the unit secretary, and in post-survey open-ended question. Resistance was also marked by a low completion rate of meal break check sheets. There were 37 (16%) shifts which had completed meal break check sheets. Fourth, even though the purpose of the study was to increase the number of nurses taking a scheduled meal break, there was initially a low number of clocked no meal breaks that averaged 8.58% of nursing shifts for January through August 2014. The impact of the project may not have been a significant impact due to the initial low number of reported missed meal breaks.

Fifth, the literature did not identify a validated tool to meet the needs of the project and the MBIS tool utilized was a limitation due to no construct validity. Finally, questions on the MBIS offered a wide range of neutrality for responses. This had the potential to wash responses to undetectable statistical significance.

Reflections on the Practice Innovation Project

Reflections on the PIP allow for identification of items that could use improvement. Helping the nurses to understand why this project was being conducted and the evidenced-based literature behind it could be improved. Spending more time with the nurses, away from patient care, to educate them on the evidenced-based literature could serve to help. The time away from patient care could have afforded quality time for a conversation about the program and the nurse's thoughts or questions. A one week time frame could not have been long enough to be able to reach each nurse and allow them to listen to the information away from interruptions.

The second item would have been to supply the pre and post-surveys with an identification marker. This would have allowed the surveys to be paired for better analysis of significance. If the surveys' were able to be paired, there is a possibility that the results of this project would have been more significant.

Third, the MBIS provided limited validity to measure the intervention. More development and testing of the MBIS tool is needed to ensure the results can be replicated and that the tool measures what it says it is measuring. The use of the NDNQI survey would have provided a validated tool for measurement that could have generalized findings for publication and future studies. The PIP location did not have access or experience with the NDNQI survey. The PIP facility utilizes annual employee surveys that had been distributed months before the PIP and the employee survey did not address meal breaks for their staff.

Fourth, the MBIS had a wide range of responses that allowed for neutral responses. The majority of the questions did not produce a statistical significance and could be a result of the neutrality of the MBIS. This could have been corrected by offering more decisive responses with fewer options. This would have also produced a clear statistical analysis between pre and post surveys.

Recommendations for future practice

Two common topics of concern from the ICU nurses were leadership support and role conflict. Discussion took place with rounding before the intervention and many nurses had similar concerns with their work environments. Leadership support and role conflict can be successfully managed and improved (Brinkert 2010; Riahl, 2010).

Increased support from leadership and corporate leaders was stated as a desire from nurses with rounding and on free text responses on post-surveys. Nurses frequently stated in conversation they did not feel they were valued or supported by the high level leaders at the facility. Some stated they did not feel the staffing was adequate to provide enough time for breaks. Night shift nurses reported most the inability to receive meal breaks due to only two nurses on the floor and a lack of support staff. Riahl (2011) found leadership recognition to nurses for job performance and accomplishments provided a reduction in reported occupational stress. Taking time to engage in a conversation with these nurses and provide formal policies can show them they are supported by leadership and can help improve the work environment (Riahl, 2011).

Role conflict between nursing colleagues was witnessed with rounding and on free text responses on post-survey. A common theme was an intergenerational conflict

between seasoned nurses not feeling comfortable in leaving patients with less experienced ICU nurses. Intergeneration conflict is a growing source of stress on both the nurse/patient and the nurse/colleague (Brinkert, 2010). Programs that provide a mentor program have helped to reduce the role conflicts between new and seasoned nurses. Conflict management workshops show positive impacts on nurses attending mandatory training and reported benefits at three months post training. Mentor programs and conflict resolution workshops should be considered to help ease the tension between these nursing colleagues (Brinkert 2010; Riahl, 2010).

Another important concept to take from this project is the Maslow's theory of hierarchy of human needs. Paris and Terhaar (2011) were successful in their break initiative to promote a healthy work environment by following Maslow's theory. The nurses basic physiological needs must be met before you can expect to help them achieve higher levels of functioning. Meal breaks are the foundation to aiding the nurse to perform at their highest abilities. Nurses stated appreciation for the attempt to help them achieve meal breaks in this project.

The stakeholder acknowledged the intervention was valuable to the unit and their staff. The stakeholder believes the intervention brought awareness to management on the importance of protecting meal breaks for ICU nurses. They intend to continue education on the importance of meal breaks and commit to continual pursuit of opportunities to ensure meal breaks are successful for the ICU nurses (A. Mills, personal communication, March 3, 2015).

Conclusion

The creation of a healthy work environment is vital to help alleviate stressors in nurses. Scheduling meal breaks offers a plan for nurses to ensure meal breaks can be achieved during their shift at work. Nursing leaders should continue to formulize plans that encompass team work and leadership support to ensure the nurse's meal breaks are protected.

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Appendix A

Meal Break Impact Survey

Thank you for taking time to give your input on this survey. This survey is used to gather information about how meal breaks impact a nurse. Meal breaks for this survey are defined as time free from patient care where the nurse is able to sit down and consume nourishment for the shift. The term shift should be referred to as any 8 consecutive hours worked on the floor doing patient care. It will take you approximately 10 minutes to complete this survey. Please choose the answer that best relates to your opinion or knowledge. Thank you again for taking time to participate. Taking this survey implies consent to participation of the study.

Section A: Demographics

1) What is your gender?

Male Female

2) What is your age category?

20-29 30-39 40-49 50-59 60+

3) How many years have you been a RN? (Please write in number)

4) How many years have you been a RN in the ICU? (Please write in number)

5) Relationship/Family Status

Single In a relationship without children Single with children In a relationship with children

Section B: Meal Breaks

6) Meal breaks are important to me.

(1) Strongly agree (2) agree (3) neutral 4) disagree (5) strongly disagree

7) I am satisfied with the care I provide my patients when I am not able to take a meal break.

(1) Strongly agree (2) agree (3) neutral (4) disagree (5) strongly disagree

8) I am more satisfied with my job when I am able to take a meal break.

(1) Strongly agree (2) agree (3) neutral (4) disagree (5) strongly disagree

9) Knowing when my meal break is reduces my stress for the shift.

(1) Strongly agree (2) agree (3) neutral (4) disagree (5) strongly disagree

10) Taking a meal break increases my stress level during my shift.

(1) Strongly agree (2) agree (3) neutral (4) disagree (5) strongly disagree

11) I feel more alert and refreshed when I am able to take a meal break.

(1) Strongly agree (2) agree (3) neutral (4) disagree (5) strongly disagree

12) I have a plan for ensuring time to take my meal break within my shift.

(1) 100% of the time (2) 75% of the time (3) 50% of the time

(4) 25% of the time (5) 0% of the time

13) When my shift begins, there is a plan to ensure all staff is able to take a break.

(1) 100% of the time (2) 75% of the time (3) 50% of the time

(4) 25% of the time (5) 0% of the time

14) How often is your meal breaks interrupted because you must return to patient care?

(1) 100% of the time (2) 75% of the time (3) 50% of the time

(4) 25% of the time (5) 0% of the time

15) How often do you not take a meal break because there is no one to relieve you?

(1) 100% of the time (2) 75% of the time (3) 50% of the time

(4) 25% of the time (5) 0% of the time

16) I am able to take a meal break each shift I work.

(1) 100% of the time (2) 75% of the time (3) 50% of the time

(4) 25% of the time (5) 0% of the time

17) I am able to take a meal break within the first half of my shift.

(1) 100% of the time (2) 75% of the time (3) 50% of the time

(4) 25% of the time (5) 0% of the time

18) I am able to take 30 minutes for a meal break.

(1) 100% of the time (2) 75% of the time (3) 50% of the time

(4) 25% of the time (5) 0% of the time

19) I am satisfied with my ability to take a meal break during work.

(1) 100% of the time (2) 75% of the time (3) 50% of the time

(4) 25% of the time (5) 0% of the time

Appendix B

Literature Review

Table 9

Literature Review

CITATION	SAMPLE/ LOCATION	INTERVENTION	OUTCOME	STRENGTHS/ WEAKNESSES	EVIDENCE
Brinkert, R. (2010)	139 papers reviewed	A review of current literature on conflict communication in nursing in order to prioritize research, theory and interventions that will support nursing managers and staff Nurses.	Conflict in nursing is multifactoral and requires diligence from RN managers to handle effectively	**Strengths:** 109 total papers integrated for review of cause and solutions.	3 (A) Meta-synthesis
Buchan, J., & Aiken, L. (2008)	Main WHO regions: The America's, Europe, Eastern Mediterranean, Africa, South East Asia, and Western Pacific.	Highlights the scale of the challenge of nursing shortages, but also makes the point that there are many common challenges and a policy agenda that points to workable solutions.	Considerable variations identified across the world. Argues shortage is due to Nurses not willing to work under current circumstances.	**Strengths:** Analyzed data at the level of main WHO regions. **Weaknesses:** Data collected on Nurses vary in title and nursing duties.	3 (A) Meta-synthesis
Grant, B., Colello, S., Riehle, M., & Dende, D. (2010)	Maine Medical Center (MMC) is a 637-bed tertiary care facility and community	Method: The Magnet Model was used to identify success factors related to a practice change and to evaluate the	Success factors for implementation of a practice change can be illuminated	**Strengths:** The Magnet Model provides an exceptional framework for	2 (A) Quasi-Experimental

	hospital in Portland Maine. n =1700 direct care Nurses	nursing practice environment. Purpose: To discuss the new Magnet Model as it relates to the successful implementation of a practice change	by aligning environmental characteristic to the components of the new Magnet Model,	building an agile and dynamic work force. Thoughtful consideration of the components and inter-relationships represented in the new model can help to both predict and ensure organizational vitality.	
Mealer M, Jones J, Newman J, McFann K, Rothbaum B, &Moss M. (2011)	3500 randomly selected ICU Nurses across the United States. 1239 of the mailed surveys were returned for a response rate of 35%, and complete data was available on a total of 744 Nurses	Surveys were mailed to and included: demographic questions, the Posttraumatic Diagnostic Scale, Hospital Anxiety and Depression Scale, Maslach Burnout Inventory and the Connor–Davidson Resilience Scale.	Resilience was independently associated with a lower prevalence of posttraumatic stress disorder and burnout syndrome in intensive care unit Nurses.	**Strengths**: Large sample results. Solid data collected to show pattern of trends.	3 (A) Qualitative
Paris, L., & Terhaar, M. (2011)	300 bed, community medical center in a large metropolitan area in the	Development of a rapid-design process to change the approach to performance improvement so as to increase engagement,	Nurses moved in the direction of attending more diligently to their personal needs and the	**Strengths:** Effective development of program that can be translatable to multiple	2 (A) Quasi-Experimental

	Mid-Atlantic region. Approximately 1200 Nurses are employed; 900 provide direct patient care.	empowerment, effectiveness, and the quality of the professional practice environment. Meal and non-meal breaks were identified as the target area for improvement.	safety of their patients by taking seriously the importance of adequate break times.	areas of nursing.	
Stefancyk, A. (2009)	White 10, a 20 bed general medical unit at Massachusetts General Hospital	One hour off unit break to launch Transforming Care at the Bedside to ease stress of bedside nursing.	Nurses worked together to shift a culture to achieve one-hour breaks and implemented an institution wide program with success	Strengths: Positive results from evidence based literature. Weaknesse ss: Small study, no data collected.	3 (C) Qualitative

Appendix C

Human Subjects Form

Is My Project Human Subject Research?

Federal regulations and Regional Health IRB policy requires that **ALL** research projects involving **humans as subjects** (including involvement of humans in one or more of the categories of research exempted or waived under the federal regulations), **OR the use of identifiable protected health information** be reviewed and approved by an IRB **PRIOR** to initiation of any research related activities, including recruitment and screening activities per the Regional Health Human Research Protection Program policy (RI RCP-8220-103). The Regional Health IRB is the sole body designed to make human subject research determinations at Regional Health.

Some categories of research are difficult to discern as to whether they qualify as human subject research. The Regional Health IRB has created this form to assist in this determination. Reviewing the entire document before answering Section II will help explain the need to answer with as much detail as possible. The IRB Coordinator will review the information provided to determine whether the study needs to be submitted to the Regional Health IRB as Human Subject Research. You will be notified as to the final determination. Any questions can be directed to the IRB Office at (605)755-9037.

Process Outline:

1. The Principal Investigator is to complete Sections I through III in their entirety.

2. The Principal Investigator will e-mail the executed form and any pertinent study documentation that will aid in making the determination to rhirb@regionalhealth.com.
3. The IRB Office will reference the definitions and the regulatory criteria (Section V through VII) against the information received.
4. The IRB Office will complete section IV, and notify the Principal Investigator via e-mail of the determination as to whether the project requires submission to the IRB.

SECTION I: GENERAL INFORMATION

Project Title: The Impact of Scheduled Meal Breanks on ICU Nurses			
Principal Investigator (PI), including degree(s): Ericka Privitt, BSN		Organization/Facility:	Rapid City Regional Hospital
Mailing Address:			
Telephone:	Fax:	E-Mail:	
Sponsor or funding source (identify all source(s) of funding for the project): None		Is this project federally funded? No	
PI is: ☒ Student @ SDSU; ☐ Faculty @ ; ☐ Employee @ ; or ☐ Other		Employee's Director or Supervisor (if a RH employee):	
Innovations Council Mentor (if nursing research): Dr. Rita Haxton, DNP		Time frame for study (projected end date): October – December 2014	
List any other IRBs that will review the study: SDSU			

SECTION II: SPECIFIC STUDY INFORMATION

1a) Does your project have a systematic investigational design? [45 CFR 46 102(d)]

"Systematic investigation" is a methodically driven investigation which includes development, testing and evaluation. Another words, does your project consist of developing an activity/plan which can be tested and evaluated?

If yes – provide a summary of the project and your hypothesis:

Hypothesis/Key questions; the key questions being asked in the research study. The research question should be clear and include: the population (participant age, gender, ethnicity, disorder, etc.), intervention (what you plan to do), control/comparison (the main alternative choice - what you are testing or comparing), and the outcome measure (specifics on how success is measured).

NO

If no – consider question 1b.

1b) Does your project contributes to generalizable knowledge? [45 CFR 46 102(d)]

"Generalizable knowledge" is knowledge based on conclusions which are drawn from particular instances that could be widely applied to populations outside the organization.

If yes – provide a summary of the project and your hypothesis:

Hypothesis/Key questions; the key questions being asked in the research study. The research question should be clear and include: the population (participant age, gender, ethnicity, disorder, etc.), intervention (what you plan to do), control/comparison (the main alternative choice - what you are testing or comparing), and the outcome measure (specifics on how success is measured).

NO

If no to questions 1a and 1b – your project is not research.

2) Does your project involve obtaining information about individuals? [45 CFR 46.102(f)]

"Human subject" is defined by the Department of Health and Human Subjects (HHS) as a living individual about whom an investigator obtains data through intervention or interaction or collects individually identifiable private information. It is defined the by the Food and Drug Administration (FDA) as an individual who is or becomes a participant in research, either as a recipient of the test article (patient) or as a control (healthy individual). In addition, unidentified tissue specimens are defined as human subjects by FDA when the research involves in vitro diagnostic device studies.

If yes – provide a detailed description of each: subject population; type of data; and specimens to be studied. Include detailed information about the specific data being collected. It will be important to note if using individually identifiable information (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)(2)] Then proceed to question 3.

NO

If no – project is not considered human subject research.

3) Does your project involve intervention or interaction with individuals? [45 CFR 46.102(f)(1). (2)]

"Intervention" is defined as physical procedures by which data is gathered or manipulations of the subject's environment.

"Interaction" includes communication or interpersonal contact.

If yes – Give detailed information about the intervention or interaction with the individual. Proceed to question 4.

YES

If no – project is not considered human subject research.

4) **Is the information being collected individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)(2)]** Please note there are 18 different identifiers of Personal Health Information listed under Section V.

NO

5) **If answering yes to question 2 - Do you intend to send data/specimens outside the Regional Health system? Please be specific as to what is being sent and where it is being sent:**

NO

6) **Do you intend to publish or present your results? If yes, please give details as to what publications or where the results <u>will</u> be presented:**

NO

If you've already developed the study documents (e.g. protocol, consent, data collection form, etc.); please attach these to your e-mail submission.

SECTION III: ATTESTATION

☒ By checking this box, you are attesting the above information is representative of the proposed activities. The Regional Health IRB acknowledges this, and accepts it in lieu of your actual signature.

Please submit this form ELECTRONICALLY to the Regional Health IRB office by attaching it to an e-mail message and sending it to rhirb@regionalhealth.com. You will receive an e-mail acknowledging receipt of this form.

SECTION VI: REGIONAL HEALTH IRB DETERMINATIONS for IRB Office Use Only

(Please allow 2 weeks for review and determination).

☐ INSUFFICIENT INFORMATION: Additional information is needed to complete the assessment of this project. Please provide the IRB Office with the follow:

_____

☑ WAIVED: the proposed activity, as described, **DOES NOT** constitute Human Subjects Research. Submission of a Regional Health IRB research application is not required.

I had a conversation with Ericka about her project on 9/11/14. She explained the premise of her project is based on evidence based cases and did not develop the activity. Ericka provided a more detailed summary of her project through the e-mail (find a copy below) which this form was accompanied and placed in our files.

☐ REQUIRED: The proposed activity, as described, **DOES** constitute Human Subjects Research. Submission of a Regional Health IRB application is required. Regional Health IRB approval must be obtained before the investigator begins their research.

9/11/2014

SECTION V: DEFINITIONS

1. "**Research**" is defined as a systematic or clinical investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
2. "**Systematic investigation**" is a methodically driven investigation which includes development, testing and evaluation.
3. "**Clinical Investigation**" is defined as any experiment that involves a test article and one or more human subject.
4. "**Generalizable knowledge**" is knowledge based on conclusions which are drawn from particular instances that could be widely applied to populations outside the organization.
5. "**Human subject**" is defined by the Department of Health and Human Subjects as a living individual about whom an investigator obtains data through intervention or interaction or collects individually identifiable private information. It is defined the by the Food and Drug Administration as an individual who is or becomes a participant in research, either as a recipient of the test article (patient) or as a control (healthy individual). In addition, unidentified tissue specimens are defined as human subjects by FDA when the research involves in vitro diagnostic device studies.
6. "**Intervention**" is defined as physical procedures by which data is gathered or manipulations of the subject's environment.
7. "**Interaction**" includes communication or interpersonal contact.
8. "**Individually identifiable private information**" is the individual's private information in which the subject's identity is or may readily be ascertained by the investigator or associated with the information. It includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. There are 18 different identifiers of Personal Health Information: names; all geographical subdivisions smaller than state; all elements of dates except year; telephone numbers; fax numbers; e-mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identification, serial, or license plate numbers; device identifiers and serial numbers; web Universal Resources (URLs); biometric identifiers, including finger and voice prints; full face photographic images and comparable images; and all other unique identifying number, characteristic, or code.

SECTION VI: DHHS CRITERIA FOR RESEARCH INVOLVING HUMAM SUBJECTS

45 CFR 46.102(f): Human subject means a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e. the identity of the subject is or may be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

1. **Does the activity meet the DHHS definition of research?**

   - The activity employs a systematic approach involving pre-determined methods for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory.
   - The activity is intended to contribute to generalizable knowledge by extending the results beyond a single individual or internal unit.

2. **Does the activity involve human subjects according to the DHHS definition?**

   - The proposed activity involves obtaining information about living individuals.
   - The investigator obtains specimens or data through intervention or interaction with individuals (e.g. prospective data collection, interviews, surveys, physical procedures, manipulations of the subject's environment, private or limited access internet sites, or any other direct contact or communication of an individual).
   - The investigator is obtaining individually identifiable information about living individuals (e.g. chart reviews, lab studies on existing tissues or specimens, information from data or tissue repository).
   - The data or specimens are received by or provided to the investigator with identifiable private information.
   - The data or specimens are coded and the investigator has access to a link that would allow the data or samples to be identified.

SECTION VII: FDA CRITERIA FOR RESEARCH INVOLVING HUMAN SUBJECTS

1. Is the activity subject to FDA human subject regulations?

- The activity is a *clinical investigation* involving a product regulated by the FDA (i.e. Drug, biological, medical device, food additive, color additive, electronic product). *Clinical Investigation* is defined as any experiment that involves a test article and one or more human subjects.
- The activity involves the use of a drug, device, or biologic, excluding an "off-label" FDA agent in the course of medical practice, in one or more human subjects.
- The results of the project are required to be submitted to or held for inspection by the FDA.
- The activity involves the testing of a medical device using tissue specimens from one or more human subjects, and the results are being submitted to the FDA for approval of the device.

2. Does the activity involve human subjects according to the FDA regulations?

- The activity involves one or more individuals who are or become participants in research, either as a recipient of the test article (i.e. drug, biological product, medical device, food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug & Cosmetic Act), or as a control.
- The activity involves one or more individuals who participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control.

SECTION VIII: Reviewer considerations

To decide whether something is research, it is important to consider the following questions in order. The project will not be considered research if any question is answered with "no":

1. Is the activity an Investigation (a searching inquiry for ascertaining facts; detailed or careful examination)?
2. Is the investigation Systematic (carried out according to a plan)?
3. Is the systematic investigation Designed (following a behavior devised) to Develop (form the basis of in the future) or Contribute (add to) Knowledge (facts and understanding)?
4. Is the knowledge the systematic investigation is designed to develop or contribute Generalizable (widely and universally applicable)?

From: ericka privitt

Sent: Tuesday, September 02, 2014 12:58 PM

To: RH IRB

Cc: Haxton, Rita

Subject: Submission of IRB

To whom it may concern,

I have completed the attached form for an Innovation Project I have been working with Dr. Haxton and Angie Mills to implement into the ICU. This study is a requirement for the Doctorate of Nursing Practice degree completion through SDSU.

A synopsis of the program is to implement scheduled meal breaks to ensure meal breaks are able to be taken and stress reduction to ICU Nurses.

The first step will be to have ICU Nurses complete a survey via Survey Monkey to collect data on their stress level and how they feel about and are able to take meal breaks. This will require 2 weeks to collect PRE data

Implementation of the program will be having the Nurses declare a break buddy and set a goal time for a meal break. (literature states having a plan will help ensure meal breaks). This will be recorded with patient assignments for the day and placed on the board with patient assignments to visualize the plan.

Charge RN, directors for the ICU, and DNP student will make rounds as time permits to evaluate if breaks are being taken and encouragement to take breaks. (No punishment or reprimand will be done if breaks are not done)

Implementation will be for 4 weeks

A second survey will be done via Survey Monkey to collect data again to evaluate for areas of improvement. This will also take 2 weeks to collect POST data. Surveys will all be anonymous and only aggregate analysis will be collected. Please let me know if you have further questions or concerns.

Thank you, Ericka, RN BSN SDSU Graduate Nursing Student

RE: IRB Exemption

From: SDSU IRB (SDSU.IRB@sdstate.edu)

Sent: Mon 9/22/14 11:10 AM

To: Privitt, Ericka Larae - SDSU Student

Ms. Privitt,

I would agree with the Regional Health IRB's determination that this activity does not appear to meet the definition of research, and therefore is excluded from human subject's policies and procedures.

Please keep a copy of this email as evidence of this determination.

Sincerely,

Norm

Norman O. Braaten, PhD, CPIA

Research Compliance Coordinator

South Dakota State University

Appendix D

Stakeholder Agreement

DNP Capstone Site and Stakeholder Agreement

Complete this document and submit to Robin Arends

I agree to serve as Capstone Project Stakeholder to the DNP student named in this agreement.

Name of Stakeholder:

Signature of Stakeholder:

Name of DNP student:

Signature of DNP student:

Date:

PIP Project Site: